

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Looper et al.

Title: SURGICAL DEVICE WITH
MALLEABLE SHAFT

Appl. No.: 09/785,374

Filing Date: 02/16/2001

Examiner: M. Patel

Art Unit: 3743

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July 13, 2004
(Date of Deposit)

REPLY BRIEF

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 1.193(b)(1), this Reply Brief is being filed in triplicate.

DISCUSSION

In the Examiner's Answer, the Examiner reads far too much into a single paragraph found in the *Makower* reference; ignores the plan language teachings of *Makower* with respect to choice of materials; and adds two new, never-before presented arguments, one of which ignores much of the language of the claims and the discussion in the specification, and one of which contradicts all of the Examiner's prior arguments.

In particular, the Examiner continues the prohibited use of "hindsight gained from knowing that the inventor[s] choose to combine the particular things in this particular way." The Examiner somehow finds in the oft cited column 7, lines 4-16 of *Makower*, the "first tube configured to kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube." (Examiner's Answer, Page 3). The Examiner even goes so far as to argue, "Makower is silent to the specific range of bending moment." (*Id.*). However, nothing in the cited paragraph suggests the presence of "bending radius", let alone a "specific range of bending moment":

“The tubular support 11 can be made out of any material appropriate for the nature of its use and in particular a medical grade plastics, metals or ceramics may be used, however, the choice of material will undoubtedly be determined by the function of the particular configuration. While elongate tube 41 can be easily extruded U-shaped channels 40, machining in addition to extrusion, or molding may be needed to obtain the desired cross-sectional configuration necessary. It is expected that skilled artisans will be able to fashion a tubular support 11 from single or multiple pieces in a way which provides a thin wall and allows a maximum passage 16 therethrough while providing adequate strength for carrying the members 15 at the distal end 13 thereof.”

(*Makower*, column 7, lines 4-16). The incongruity of the Examiner’s position is exposed with respect to the Examiner’s argument that *Makower* is configured to kink resistant and fatigue resistant: of course it is kink and fatigue resistant – it doesn’t bend, let alone provide the claimed malleability. For this reason alone, the rejection is improper and should be overturned.

In addition, the Examiner continues to argue that “it would have been obvious to one of ordinary skill in the art to provide a tube with a specific bending moment based on the intended use and function as disclosed in *Makower*”, again cited to column 7, lines 4-16. In point of fact, column 7, lines 4-16 discusses the choice of material as a means to achieve the ends of particularly shaped cross-sectional configurations, not providing a bending moment. Not only is the concept of providing a tube with a bending moment absent, *Makower* actually teaches away from the Examiner’s argument of provide a tube with a bending moment based on the intended use and function. For this additional reason, the rejection is improper and should be overturned.

Finally, in her Answer the Examiner makes two new arguments that had not previously been made:¹ First, the Examiner cites to the first definition of “malleable” from the American Heritage Dictionary of the English Language, Third Edition. Initially, the complete definition (from American Heritage Dictionary of the English Language, Fourth Edition (2000)(available at <http://www.bartleby.com/61/27/M0062700.html>)) is:

1. Capable of being shaped or formed, as by hammering or pressure: *a malleable metal*.
2. Easily controlled or influenced; tractable.
3. Able to adjust to changing circumstances; adaptable: *the malleable mind of the pragmatist*.

It is clear from the context that the term “malleable” with respect to the tube of the present invention means, “capable of being shaped or formed, easily controlled or influenced.”

In addition, the Examiner’s argument in this regard ignores the claim language. The claim language with respect to the tube is, “a first tube made of a malleable material . . . , the first

¹ These new arguments are, of course, prohibited by 37 C.F.R. § 1.193(a)(2), which states, “[a]n examiner’s answer must not include a new ground of rejection”

tube configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the first tube.” Thus, the claims themselves further define the malleable tube.

Still further, the application itself dicusses the tube as,

“the shaft member 314 is sized and configured to be easily bendable, to be highly kink resistant, and to be highly fatigue resistant. The shaft member 314 is easily bendable in response to the application of a reasonable bending moment. A reasonable bending moment is that which an average human can exert to bend the shaft member 314 with minimal effort.”

(Application, page 13). For this additional reason, the rejection is improper and should be overturned.

The Examiner’s second new argument consists of the inevitable “inherency” argument. The Examiner now argues that because the “Applicant broadly recites ‘some bending radius’” (emphasis in original), and because the metal or plastic tube of *Makower* “would and are inherently capable of being bent at some bending radius”, the claim is obvious. In other words, everything has some theoretical bending radius, no matter how negligible.

The Examiner’s second new argument apparently concedes that the tube of *Makower* is not malleable (as defined above). Since the claim language includes not only the language regarding the bending moment, but also the language regarding malleable, the rejection is improper and should be overturned. In addition, the Examiner’s new scenario that anything is “inherently capable of being bent at some bending radius” ignores the further claim language, that the “tube [is] configured to be kink resistant”. Rest assured, hammering a metal tube of *Makower* to bend it around “some bending radius” would result in kinks. For this additional reason, the rejection is improper and should be overturned.²

CONCLUSION

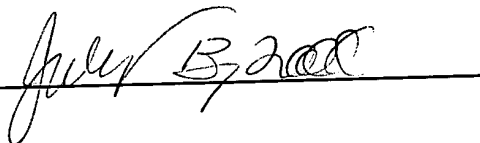
The Examiner has failed to meet her “initial burden of presenting a *prima facie* case of obviousness.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

² In addition to these two new grounds for rejection, in the Examiner’s Answer for the first time the Examiner points out that the claim language does not recite fatigue resistance. The Examiner is correct. For all the reasons discussed herein, Applicant believes that the claims should be allowed even in the absence of this language; however, in a phone call to the Examiner on 30 June 2004, Applicant’s representative offered to amend the claims to include fatigue resistance if that would put the application in condition for allowance. In a voice mail received by the Applicant’s representative 6 July 2004, the Examiner declined. In the event the Board disagrees with the Applicant and believes that the claims would only be allowable with the addition of this language or if the Board believes that further clarification as to malleable or bending moment is required in the claims, the Board is invented to so indicate and remand to the Examiner under 37 C.F.R. 1.196(c).

Claims 1, 3-13, and 15-21 would not have been obvious in light of *Makower* to a person of ordinary skill in the art at the time the invention was made under 35 U.S.C. § 103(a). *Makower* does not teach, disclose, or suggest the use of a malleable material which is kink resistant and able to bend about a bending radius. Thus, the rejection is improper and should be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Accordingly, favorable consideration and allowance of the application is respectfully requested.

Respectfully submitted,

Date



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